



S/N 10/764,428

PATENT

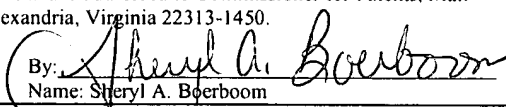
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                   |   |                 |               |
|-------------------|---|-----------------|---------------|
| Applicant:        | SIMMONS   | Examiner:       | P. HUYNH      |
| Serial No.:       | 10/764,428  | Group Art Unit: | 1644          |
| Filed:            | JANUARY 23, 2004  | Docket No.:     | 11669.120USU1 |
| Confirmation No.: | 6080  | Customer No.:   | 23552         |
| Title:            | METHODS FOR PRODUCING HUMANIZED ANTIBODIES AND<br>IMPROVING YIELD OF ANTIBODIES OR ANTIGEN BINDING<br>FRAGMENTS IN CELL CULTURE |                 |               |

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 639593725 US  
Date of Deposit: February 13, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, Mail Stop Amendments, Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450.

By:   
Name: Sheryl A. Boerboom

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

A copy of any foreign patent document or "Other Document" listed on the Form 1449 is enclosed, in accordance with 37 C.F.R. § 1.98(a)(2). Because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. patent publications listed on the enclosed Form 1449 are not provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to

establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

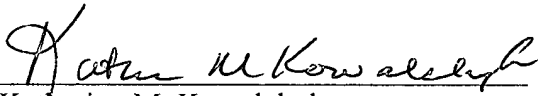
Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

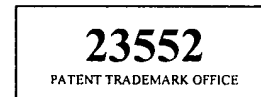
Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P. O. Box 2903  
Minneapolis, Minnesota 55402-0903  
612.332.5300

Date February 13, 2006

  
Katherine M. Kowalchyk  
Reg. No. 36,848  
KMK:sab



FORM 1449\*

## INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:

11669.120USU1

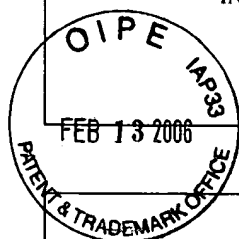
Application Number:

10/764,428

Applicant: SIMMONS

Filing Date: 01/23/04

Group Art Unit: 1651



## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NO. | DATE       | NAME           | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|---------------------|--------------|------------|----------------|-------|----------|-------------------------------|
|                     | 5,225,539    | 07/06/1993 | WINTER         |       |          |                               |
|                     | 5,693,761    | 12/02/1997 | QUEEN ET AL.   |       |          |                               |
|                     | 5,821,337    | 10/13/1998 | CARTER ET AL.  |       |          |                               |
|                     | 5,859,205    | 01/12/1999 | ADAIR ET AL.   |       |          |                               |
|                     | 5,869,619    | 02/09/1999 | STUDNICKA      |       |          |                               |
|                     | 6,800,738 B1 | 10/05/2004 | CARTER ET AL.  |       |          |                               |
|                     | 6,479,284 B1 | 11/12/2002 | MARASCO ET AL. |       |          |                               |
|                     | 6,881,557 B2 | 04/19/2005 | FOOTE          |       |          |                               |
|                     |              |            |                |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|--------------|------|---------|-------|----------|-------------|----|
|  |              |      |         |       |          | YES         | NO |
|  |              |      |         |       |          |             |    |
|  |              |      |         |       |          |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |  |  |
|--|--|--|
|  |  | Carter et al., "High Level <i>Escherichia Coli</i> Expression and Production of a Bivalent Humanized Antibody Fragment", <u>Bio/Technology</u> , 10:163-167 (1992) |
|  |  | Chomczynski et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", <u>Anal. Biochem.</u> , 162:156-159 (1987) |
|  |  | Chothia et al., "Structural Repertoire of the Human VH Segments", <u>J. Mol. Biol.</u> , 227:799-817 (1992)  |
|  |  | Foote et al., "Antibody Residues Affecting Conformation of the Hypervariable Loops", <u>J. Mol. Biol.</u> , 224:487-499 (1992)                                     |
|  |  | Hampe et al., "A novel monoclonal antibody specific for the N-terminal end of GAD65", <u>Journal of Neuroimmunology</u> , 113:63-71 (2001)                         |
|  |  | Hansen et al., "Monoclonal Antibodies Identifying a Novel T Cell Antigen and Ia Antigens of Human Lymphocytes", <u>Immunogenetics</u> , 10:247-260 (1980)          |
|  |  | Henikoff et al., "Amino acid substitution matrices from protein blocks", <u>Proc. Natl. Acad. Sci. USA</u> , 89:10915-10919 (1992)                                 |
|  |  | Jin et al., "High Resolution Functional Analysis of Antibody-Antigen Interactions", <u>J. Mol. Biol.</u> , 226:851-865   |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

|   |                                 |                                   |
|---|---------------------------------|-----------------------------------|
| <b>FORM 1449*</b><br><b>INFORMATION DISCLOSURE STATEMENT</b><br><br><b>IN AN APPLICATION</b><br><br>(Use several sheets if necessary) | Docket Number:<br>11669.120USU1 | Application Number:<br>10/764,428 |
|   | Applicant: SIMMONS              |                                   |
|   | Filing Date: 01/23/04           | Group Art Unit: 1651              |

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|  | (1992)   |
|  | Jonsson et al., "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance and a Sensor Chip Technology", <u>BioTechniques</u> , 11:620-627 (1991)  |
|  | Licea et al., "FAB Fragments of the Monoclonal Antibody BCF2 are Capable of Neutralizing the Whole Soluble Venom from the Scorpion <i>Centruroides Noxius</i> Hoffmann", <u>Toxicon</u> , 34(8):843-847 (1996)   |
|  | MacCallum et al., "Antibody-antigen Interactions: Contact Analysis and Binding Site Topography", <u>J. Mol. Biol.</u> , 262:732-745 (1996)   |
|  | Martin et al., "Structural Families in Loops of Homologous Proteins: Automatic Classification, Modelling and Application to Antibodies", <u>J. Mol. Biol.</u> , 263:800-815 (263)  |
|  | Mhashilkar et al., "Inhibition of Human Immunodeficiency Virus Type I Replication <i>in Vitro</i> in Acutely and Persistently Infected Human CDR4 <sup>+</sup> Mononuclear Cells Expressing Murine and Humanized Anti-Human Immunodeficiency Virus Type I Tat Single-Chain Variable Fragment Intrabodies", <u>Human Gene Therapy</u> , 10:1453-1467 (1999) |
|  | Morea et al., "Antibody Modeling: Implications for Engineering and Design", <u>Methods</u> , 20:267-279 (2000)   |
|  | Padlan, E.A., "A Possible Procedure for Reducing the Immunogenicity of Antibody Variable Domains while Preserving their Ligand-Binding Properties", <u>Mol. Immunol.</u> , 28(4):489-498 (1991)  |
|  | Padlan et al., "Identification of specificity-determining residues in antibodies", <u>FASEB J.</u> , 9:133-139 (1995)  |
|  | Rosok et al., "A Combinatorial Library Strategy for the Rapid Humanization of Anticarcinoma BR96 Fab", <u>The Journal of Biological Chemistry</u> , 271(37):22611-22618 (1996)   |
|  | Rudikoff et al., "Single amino acid substitution altering antigen-binding specificity", <u>Proc. Natl. Acad. Sci. USA</u> , 79:1979-1983 (1982)  |
|  | Rutgeerts et al., "Efficacy and Safety of Retreatment With Anti-Tumor Necrosis Factor Antibody (Infliximab) to Maintain Remission in Crohn's Disease", <u>Gastroenterology</u> , 117:761-769 (1999)  |
|  | Selisko et al., "Antibody BCF2 Against Scorpion Toxin Cn2 From <i>Centruroides noxius</i> Hoffmann: Primary Structure and Three-Dimensional Model as Free Fv Fragment and Complexed With Its Antigen", <u>PROTEINS: Structure, Function and Genetics</u> , 37:130-143 (1999)   |
|  | Tamara et al., "Structural Correlates of an Anticarcinoma Antibody: Identification of Specificity-Determining Residues (SDRs) and Development of a Minimally Immunogenic Antibody Variant by Retention of SDRs Only", <u>The Journal of Immunology</u> , 164:1432-1441 (2000)  |
|  | Tan et al., ""Superhumanized Antibodies:Reduction of Immunogenic Potential by Complementarity-Determining Region Grafting with Human Germline Sequences :Application to Anti-CD28", <u>The Journal of Immunology</u> , 169:1119-1125 (2002)  |
|  | Tomlinson et al., "The Structural Repertoire of the Human Vk Domain", <u>EMBO J.</u> , 14(18):4628-4638 (1995)   |
|  | Tramontano et al., <u>J. Mol. Biol.</u> , 215:175-182 (1990)   |
|  | Wu et al., "An Analysis of the Sequences of the Variable Regions of Bence Jones Proteins and Myeloma Light Chains and Their Implications for Antibody Complementarity", <u>J. Exp. Med.</u> , 132:211-250 (1970)   |
|  | Wu et al., "Humanization of a Murine Monoclonal Antibody by Simultaneous Optimization of Framework and   |

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|   | Applicant: SIMMONS              |                                   |
|   | Filing Date: 01/23/04           | Group Art Unit: 1651              |

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|  |  | CDR Residues", <u>J. Mol. Biol.</u> , 294:151-162 (1999)   |
|  |  | Ye et al., "Gene Synthesis and Expression in <i>E. Coli</i> for PUMP, a Human Matrix Metalloproteinase", <u>Biochem. Biophys. Res. Comm.</u> , 186(1):143-149 (1992) |



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